Hello Providers,

This communication is being sent on behalf of Bethany Gadzinski at the Idaho Department of Health & Welfare. Please see the email below.

Thank you,

BPA Provider Network Management

Vivitrol (naltrexone for extended-release injectable suspension): Medication Guide Required for Patients

Audience: Substance Abuse healthcare providers, patients

Alkermes and FDA notified healthcare professionals and patients of an update to the Warnings, Information for Patients, and Dosage and Administration sections of the Prescribing Information to strengthen language regarding the risk of injection site reactions based on postmarketing reports that had been received prior to June 2009.

FDA requires that a Medication Guide, which communicates this and other important information about treatment be provided to all patients. Healthcare professionals should also counsel patients about the risks and benefits of Vivitrol before an initial prescription, including those risks and benefits set forth in the new Medication Guide and Prescribing Information, and should ensure that patients understand these risks.

Read the complete MedWatch 2010 Safety summary, including links to the Dear HCP letter, the revised Prescribing Information and the new Medication Guide, at:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm210755.htm

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